REMARKS

The Applicants thank the Examiner for the thorough consideration given the present application. Claims 6, 9, and 11 are cancelled without prejudice to or disclaimer of the subject matter contained therein. Claims 1-5, 7, 8, 10, and 12 are pending. Claims 1, 2, 4, 5, 7, and 10 are amended, and claim 12 is added. Claim 1 is independent. The Examiner is respectfully requested to reconsider the rejections in view of the amendments and remarks set forth herein.

Allowable Subject Matter

The Examiner states that claim 7 would be allowable if rewritten in independent form.

The Applicants thank the Examiner for the early indication of allowable subject matter in this application. Rather than rewriting objected-to claim 7 in independent from at this time, instead, independent claim 1 is amended herein to include a novel combination of elements not suggested by the references cited by the Examiner. Accordingly, claim 1 is now in condition for allowance.

Foreign Priority Claim

The Examiner has acknowledged the Applicants' claim for foreign priority.

Revised Title

The Title has been revised to correct a typographical error.

Revised Abstract of the Disclosure

The Abstract of the Disclosure has been revised merely to place it in better form.

Substitute Specification

In accordance with MPEP §608.01(q), Applicants herewith submit a substitute specification in the above-identified application. Also included is a marked-up copy of the original specification which shows the portions of the original specification which

are being added and deleted. Applicants respectfully submit that the substitute specification includes no new matter and that the substitute specification includes the same changes as are indicated in the marked-up copy of the original specification showing additions and deletions.

Because the number of amendments which are being made to the original specification would render it difficult to consider the case, or to arrange the papers for printing or copying, Applicants have voluntarily submitted this substitute specification. Accordingly, Applicants respectfully request that the substitute specification be entered into the application.

Drawings

Two sheets of revised formal drawings are attached to properly label FIGS. 2A-2E, 3A, and 3B. Also, reference numerals included in the specification are now shown in FIGS. 3A and 3B. No new matter has been added.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 1-11 stand rejected under 35 U.S.C. § 112, second paragraph. This rejection is respectfully traversed.

In order to overcome this rejection, Applicants have cancelled claim 9 and have amended claim 10 to correct each of the deficiencies specifically pointed out by the Examiner. Applicants respectfully submit that the claims, as amended, particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

Claims 1-6 and 8-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bowen (U.S. 2,127,903) in view of Datta et al (U.S. 2003/0144730).

Further, claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Bowen in view of Stinson (U.S. 6,174,330) and further in view of Hyodoh et al U.S. 2003/0149475). These rejections are respectfully traversed.

Complete discussions of the Examiner's rejections are set forth in the Office Action, and are not being repeated here.

While not conceding the appropriateness of the Examiner's rejection, but merely to advance prosecution of the instant application, independent claim 1 has been amended to recite a combination of elements in a biodegradable common bile duct stent for longitudinal and tranverse incisions at multiple parts of a common bile duct or a common hepatic duct,

wherein the stent includes a tube structure with thin and continuous walls, and includes an outer shape substantially equal to an anatomical shape of the common bile duct,

wherein the stent is formed with multiple parts, each of the multiple parts having an outer diameter substantially equal to 1 to 3 times an inner diameter of corresponding parts of the common bile duct of a healthy person,

wherein the stent is made of biodegradable polymeric material including X-ray opaque components.

Applicants respectfully submit that this combination of elements as set forth in independent claim 1 is not disclosed or made obvious by the prior art of record, including Bowen and Datta et al.

The Patentability Of The Present Invention

Independent claim 1 includes the following technical features:

(1) Continuity and shielding function of the stents of the present invention;

(2) Inclusion of the opaque material in the stents; and

(3) Shape of the stent wall.

In contrast to independent claim 1 of the present invention, Bowen (U.S. 2,127,903) relates to various kinds of surgical tubes made of absorbable animal tissues. The present application relates to CBD stents made of biodegradable synthetic

polymers. The materials and the processing methods of the present invention are entirely different from Bowen. Bowen does not teach the present invention at all.

Regarding Datta et al. (U.S. US2003/0144730), this document merely discloses concentric bi-component filaments are wound into tubes. The difference in biodegradation rate of the shell and of the core of the filament are utilized to protect the stents from breaking into large fragments and bringing damage to human lumens. Their use is mainly to maintain open passageways such as prostatic urethra etc. They are placed in desired human lumens by means of special devices.

However, there are following significant differences between Datta et al. (U.S. 2003/0144730) and the present invention:

(a) the stents in U.S. 2003/0144730 is of tube-shape, however they are wound of polymer filaments (Claim 1, Fig. 3 and 10), and thus are not continuous. They have the function of supporting, however they do not have the function of separation or shielding. Furthermore, they cannot be used for common bile duct exploration (CBDE) plus primary suturing. The stents in the present invention are continuous tubes with thin walls and thus have the function of supporting, separating and shielding. They can prevent the bile leakage and are suitable for CBDE plus primary suturing. They can replace the silicone rubber T-tubes currently used clinically.

(b) The stents in U.S. 2003/0144730 are delivered to desired place by special placement device (Fig.1, 2, 5, 6, 7, 8, and 9). Obviously, this placement device is not suitable to CBD. Therefore, these stents are not suitable to CBD. The stents in the present invention are placed in position during surgery and the operation is very simple and no special devices are needed. The technical solution of Datta et al. does not have these advantages.

(c) The Datta et al. device fails in preparing a biodegradable tube with proper degradation rate and not breaking down into large fragments. The CBD stents prepared in the present invention have not met such problems (bile blocking or CBD damage) in the animal trials for 110 Wistar rats and 50 dogs (see the examples, some results are published as journal articles). In short, the present application can realize

the objective of Datta et al. (U.S. 2003/0144730), while avoid its disadvantages such as non-continuality and need in special placement device.

At least for the reasons explained above, the Applicants respectfully submit that the combination of elements as set forth in independent claim 1 is not disclosed or made obvious by the prior art of record, including Bowen and Datta et al.

Therefore, independent claim 1 is in condition for allowance.

Analysis of other Documents cited in the Office Action

At Stinson (U.S. 6,174,330) relates to "bioabsorbable-radiopaque marker", which is made of biodegradable polymers and is used in "implantable endoprosthesis" that include "stent". However, this biodegradable marker is fabricated into the form of filament and is inserted in the stent. There is no statement whether the stent itself is biodegradable or not because the patent only mentions that the stent is "radiolucent". In the present application, however, the stent itself is biodegradable, the X-ray-opaque material is blended in the biodegradable polymer materials, and thus, the stent of the present invention is both biodegradable and radiopaque. The present invention is entirely different from Stinson.

U.S.6,132,471 relates to placement device for pancreatic and biliary duct stents. The device has nothing to do with the present application. In U.S. 6,132,471, the stents to be placed are made of "soft biocompatible material", i.e., "Silicon rubber" (Line 9 in Abstract, Claim 3). Silicon rubber is biocompatible but not biodegradable. In the present application, the stents are made of biodegradable materials, and cannot be fabricated based on the teaching of U.S. 6,132,471.

U.S. 2003/0149475, U.S. 2003/0139796, U.S. 2003/0181973, and U.S. 5,342,348 all relate to self-expandable devices in the form of networks. They are made of metals or alloys and thus not biodegradable at all. Among them, one document mentions biodegradable polymer material, but it is used as a drug carrier and is attached onto the stents in the form of coating, film or implants. Therefore, these documents do not teach the present application at all. It is not obvious for those

skilled in the art to obtain the present invention based on the teaching of these patents.

In view of above, these documents cannot make up for the deficiencies of Bowen and Datta et al. to teach the present invention set forth in independent claim 1.

The Examiner will note that dependent claims 1, 2, 4, 5, 7, and 10 are amended, dependent claims 6, 9, and 11 are cancelled, and dependent claim 12 is added.

All dependent claims are in condition for allowance due to their dependency from allowable independent claims, or due to the additional novel features set forth therein.

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) are respectfully requested.

CONCLUSION

Since the remaining patents cited by the Examiner have not been utilized to reject claims, but merely to show the state of the art, no comment need be made with respect thereto.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. It is believed that a full and complete response has been made to the outstanding Office Action, and that the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone Carl T. Thomsen (Reg. No. 50,786) at (703) 205-8000.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17, particularly extension of time fees.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated: **October 3, 2005**

Respectfully submitted,

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Attachments:
Substitute Specification
Two Sheets of Revised Formal Drawings

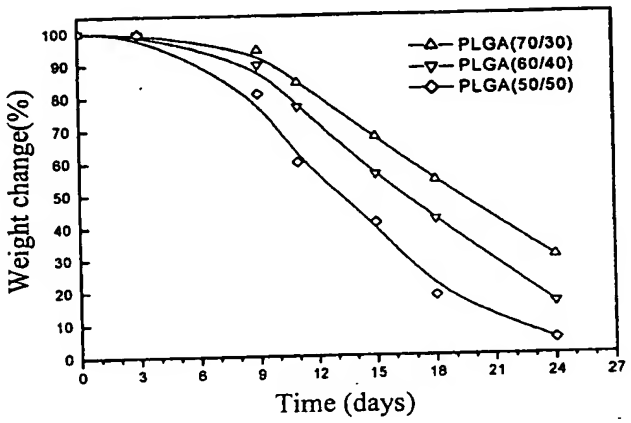

Fig.1

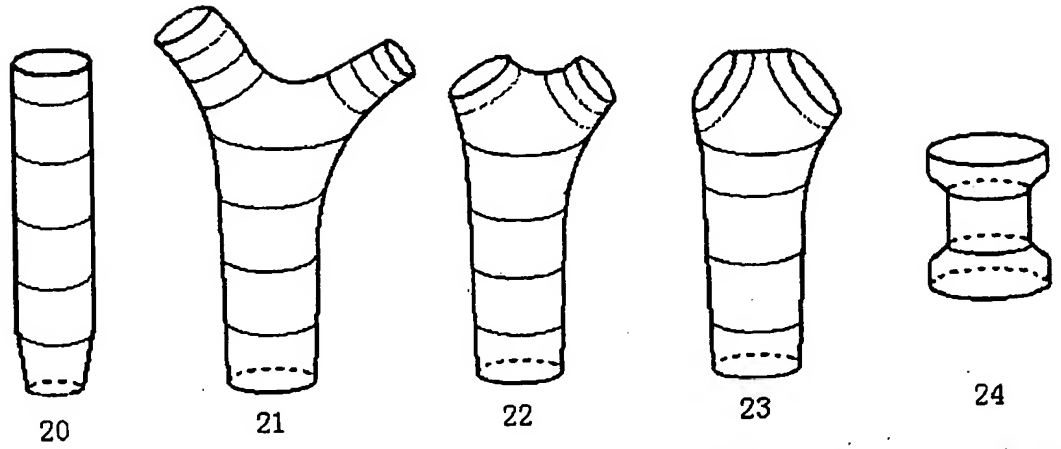

FIG. 2A FIG. 2B FIG. 2C FIG. 2D FIG. 2E

~~Fig.2~~

REPLACEMENT SHEET

~~2/2~~

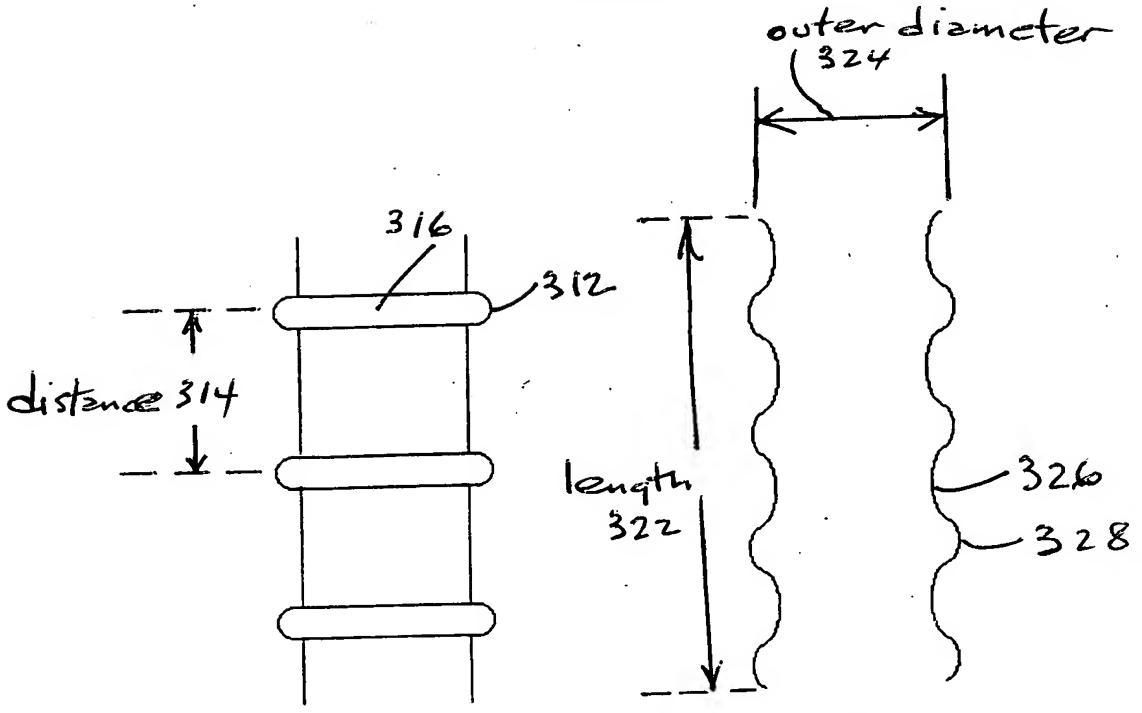

FIG. 3A

FIG. 3B

~~Fig.3~~

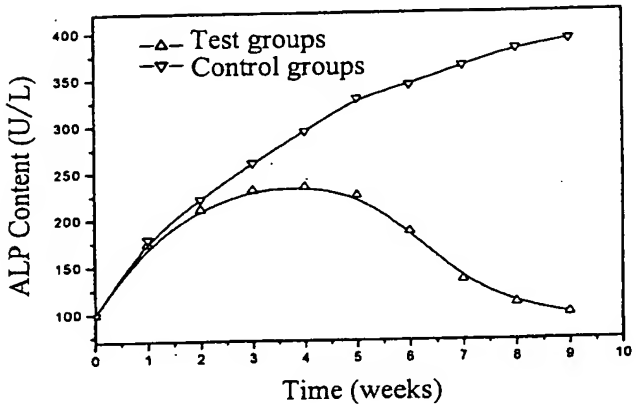

Fig.4